

<b>Notice of Allowability</b>	Application No.	Applicant(s)	
	10/022,127	PANCHAL ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment of 8-12-05, and the Examiner's Amendment/Interview Summary 10-21-05.
2. ☒ The allowed claim(s) is/are 1-7,14-18,20 and 21.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>10-21-05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                                    |
|   | 9. <input type="checkbox"/> Other _____.   |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claim 1. (Amended) An isolated oligonucleotide which encodes a synthetic suppressor tRNA comprising:

(A) a human tRNA structural gene sequence comprising no more than twenty 3' flanking residues and no 5' flanking residues, said sequence encoding an anticodon region for pairing with mRNA;

(B) an anticodon sequence contained within said anticodon region which has been modified to recognize a nonsense mutation ~~a codon different from that which is originally recognized;~~

wherein said oligonucleotide has a total length of less than 150 nucleotides.

Claim 2. (Amended) A synthetic suppressor tRNA molecule encoded by the oligonucleotide of ~~claim 4~~ claim 7.

Claim 3, line 2, the term "a" was replaced with "the."

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Claim 7, line 1, the term "isolated," was inserted immediately before the term "oligonucleotide."

Claim 14, line 1, the phrase "A nucleotide," was replaced with "An isolated nucleotide."

Claims 20-21, line 1, the term "isolated" was inserted immediately before the term "host."

The following is an examiner's statement of reasons for allowance:

Capone et al. (1988) teach that a mutant human tRNA<sup>ser</sup> gene comprising only 22 nucleotides of the 3' flanking sequence was efficiently expressed, and that another deletion mutant of the human tRNA<sup>ser</sup> gene comprising the complete removal of the 5' flanking region was efficiently transcribed. However, the reference did not teach efficient transcription of a human tRNA gene comprising both complete removal of the 5' flanking sequence and *no more than 20* base pairs of the 3' flanking sequence. In fact, the Capone et al. teach a 30% reduction in transcriptional efficiency of the deletional mutant comprising 22 base pairs of 3' flanking sequence in comparison to wild-type, and an over 80% reduction in transcriptional efficiency for a deletional mutant wherein the entire 5' flanking sequence was removed (see Table 1). Therefore, there was no motivation to further modify the tRNA gene sequence to comprise no more than 20 base pairs of 3' flanking sequence and further comprising a deletion of the entire 5' flanking sequence, wherein the total sequence of an isolated oligonucleotide comprising the gene sequence was less than 150 base pairs in length.

Additionally, the prior art describes the elucidation of the 5' and 3' extragenic control regions of tRNA genes (see for example Arnold et al., 1988), by the synthesis of chimeric tRNA genes and deletional mutants. Arnold et al. teach that sequences within the 5' flanking region of the human tRNA<sup>val</sup> genes are required for stable complex formation with at least one transcription factor, and the 3' flanking region functions to regulate the transcription of the tRNA genes, the presence of the entire 3' flanking region results in an eight-fold increase in transcription efficiency (see abstract, and page 96, last paragraph).

Therefore, at the time of the instant invention the ordinary skilled artisan would not have been motivated to modify human tRNA genes described in the prior art (see Sprinzl et al. [1984, IDS; and 1988] Green et al. and Roy et al.) by removing the entire 5' flanking sequence, and further leaving no more than 20 nucleotides of the 3' flanking sequence, and having a total length of less than 150 nucleotides.

2. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
Janet L. Epps-Ford  
Primary Examiner  
Art Unit 1633

JLE